K062410

Aug 16, 2006

510(k) Summary

SEP 26 2006

3-1. 510(k) owner (submitter)

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person	Michio Takigawa Quality Assurance Department
4) Contact person in U.S.	Koji Nishida KURARAY AMERICA INC. 600 Lexington Avenue, 26th Floor New York, NY 10022 Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676 Fax: (212)-867-3543

3-2. Name of Device

1) Trade / Proprietary name	CLEARFIL ESTHETIC CEMENT & DC BOND
2) Classification name	Dental cement (21 CFR section 872.3275. Product code: EMA)
3) Common name	Composite resin cement

3-3. Predicate device

1) PANAVIA F 2.0	510(k) Number:	K032455
	Product Code:	EMA
	21 CFR Section:	872.3275
	Applicant:	KURARAY MEDICAL INC.
2) CLEARFIL DC CEMENT	510(k) Number:	K012735
	Product Code:	EMA
	21 CFR Section:	872.3275
	Applicant:	KURARAY MEDICAL INC.
3) CLEARFIL DC CORE AUTOMIX	510(k) Number:	K043177
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	KURARAY MEDICAL INC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kuraray Medical, Incorporated
C/O Mr. Koji Nishida
Kuraray America, Incorporated
600 Lexington Avenue, 26th Floor
New York, New York 10022

SEP 26 2006

Re: K062410
Trade/Device Name: Clearfil™ Esthetic Cement & DC Bond
Regulation Number: 21 CFR 872.3275(b)
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: August 16, 2006
Received: August 24, 2006

Dear Mr. Nishida:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062410

Device Name: CLEARFIL ESTHETIC CEMENT & DC BOND

Indications for Use:

1) Cementation of crowns, bridges, inlays and onlays made of porcelain, ceramic, hybrid ceramics, composite resin or metal
2) Cementation of veneers
3) Cementation of adhesion bridges
4) Cementation of metal cores, resin cores, metal posts or glass-fiber posts

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use N/A (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Sign-Off
on of Anesthesiology, General Hospital,
Infection Control, Dental Devices

Number: K062410